AVENIO ctDNA Analysis Kits V2

The complete NGS liquid biopsy solution

AVENIO ctDNA Analysis Kits

Next-generation performance in liquid biopsies

Accelerating clinical research

From liquid biopsy to next-generation sequencing (NGS), rapid advances are underway to expand the possibilities for new discoveries in oncology.

Liquid biopsy, a novel approach to sample collection through a simple blood draw, offers exciting possibilities for use in cancer research. This minimally-invasive procedure provides easy sample access to a broad population, and enables the possibility for serial testing. Furthermore, circulating tumor DNA (ctDNA), obtained through liquid biopsy, may provide a more accurate representation of tumor heterogeneity since ctDNA are derived from delocalized tumor cells.

NGS, with its high throughput capabilities, ability to sequence multiple genes and detect multiple types of variants in a single assay, is helping to accelerate cancer research.

AVENIO ctDNA Analysis Kits V2 combine the accessibility of liquid biopsy with the power of NGS in an end-to-end tumor profiling and tumor burden monitoring solution. These assays are designed to help researchers understand the genomic complexities of cancer and accelerate new discoveries in oncology.

Liquid biopsy and NGS expand the possibilities for new discoveries in oncology

For Research Use Only. Not for use in diagnostic procedures.

The AVENIO ctDNA Analysis Kits V2: A portfolio of three NGS liquid biopsy assays

Our portfolio of assays provide researchers the **flexibility to select the panel that best meets their research needs, and enable labs to offer NGS liquid biopsy tests for various research applications from a single trusted source.**

The AVENIO ctDNA Analysis Kits V2 use intelligent panel design algorithms, molecular barcodes and error suppression methods[1] that enable researchers to interrogate mutated regions in a variety of cancer applications. The technology applies population-scale data from public cancer databases for panel design to detect and quantify cancer-specific genomic aberrations in ctDNA shed from solid tumors.[2]

Tumor Profiling

AVENIO ctDNA
Targeted Kit V2

Product Number: 09733736001

- 17 genes, 81 kb panel
- Contains genes in NCCN Guidelines[3]
- Pan-cancer panel optimized for lung cancer and colorectal cancer

Expanded Tumor Profiling

AVENIO ctDNA
Expanded Kit V2

Product Number: 09733779001

- 77 genes, 192 kb panel
- Contains emerging biomarkers relevant to clinical research and genes in NCCN Guidelines[3]
- Pan-cancer panel optimized for lung cancer and colorectal cancer

Tumor Profiling/Longitudinal Tumor Burden Monitoring

AVENIO ctDNA
Surveillance Kit V2

Product Number: 09733817001

- 197 genes, 198 kb panel
- Includes genes in NCCN Guidelines[3]
- Potential for longitudinal monitoring of lung cancer and colorectal cancer tumor burden

The Surveillance Kit panel design maximizes the number of mutations detected per subject while minimizing the panel size, enabling researchers to use the combined power of multiple mutations to increase the detection of ctDNA several fold while minimizing sequencing costs.[2]

All kits include the reagents for DNA extraction, library preparation and target enrichment, as well as software required to analyze sequencing data and generate reports. An Oncology Analysis Server, which is required to run the bioinformatics pipeline, is available from Roche.

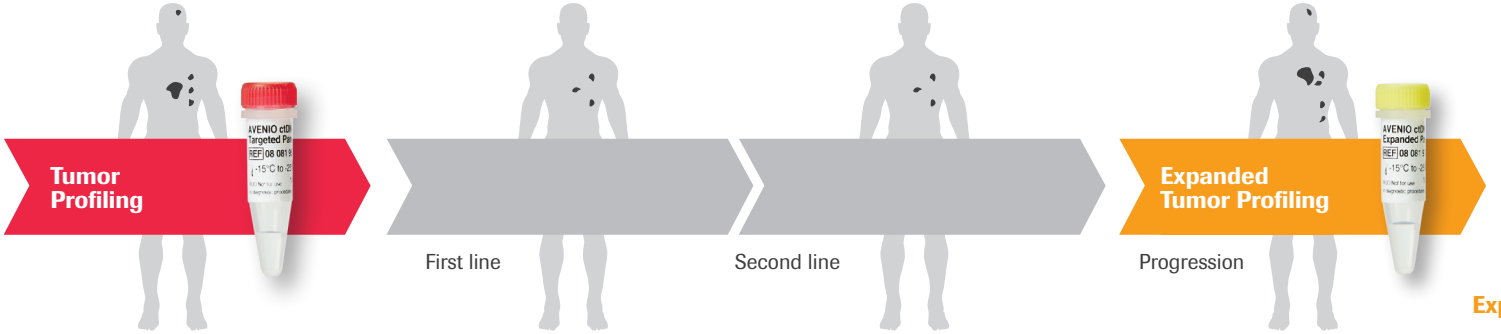
Potential research applications

The AVENIO ctDNA Analysis Kits V2 can support a variety of use cases. Here are two examples:

Example A

Targeted Kit

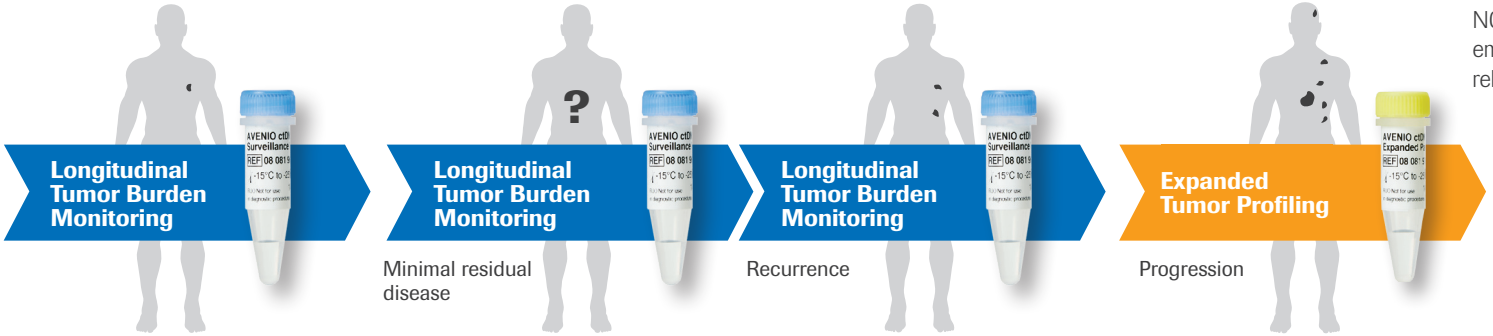
Identify biomarkers in NCCN Guidelines[3]



Example B

Surveillance Kit

Monitor tumor burden longitudinally in lung cancer and colorectal cancer



Expanded Kit

Identify biomarkers in NCCN Guidelines[3] and emerging biomarkers relevant to clinical research

All four mutation classes in a single panel

In contrast to amplicon-based approaches that are suboptimal for providing comprehensive answers, the AVENIO ctDNA Analysis Kits V2 employ **proven hybrid-capture techniques** that **enable researchers to interrogate all four mutation classes** in a single workflow.

SNV
Single Nucleotide Variant

Indel
Insertion or Deletion

Fusion

CNV
Copy Number Variant

Streamlined, end-to-end workflow

Each step of the AVENIO ctDNA workflow has been optimized to deliver **improved accuracy, efficiency and turnaround time.**[4] The workflow has been validated on the Illumina® NextSeq™ 500/550/550Dx sequencer.

Go from sample extraction to reporting in five days

Day 1	Day 2	Day 3	Day 4	Day 5
DNA Isolation	Library Generation	Target Enrichment	Sequencing	Analysis & Report

AVENIO ctDNA Analysis Kits V2

AVENIO cfDNA Isolation Kit V2

AVENIO ctDNA Library Prep Kit V2

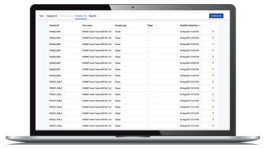
AVENIO ctDNA Enrichment Kit V2

AVENIO ctDNA Targeted, Expanded, and Surveillance Panels V2

AVENIO ctDNA Post-Hybridization Kit V2

GATCTAGATTC
GGTCCAGATTC
GATCCAGCTTC
CATCCAGATTC
GATACAGATTC
GATCCAGATGC

Illumina NextSeq 500/550/550Dx and MiSeq System†



With ctDNA Targeted, Expanded, or Surveillance Panels: AVENIO Oncology Analysis Software Requires Oncology Analysis Server

†NextSeq 500/550/550Dx instruments, MiSeq instruments, and associated sequencing reagents are manufactured and sold by Illumina and are not supplied by Roche.

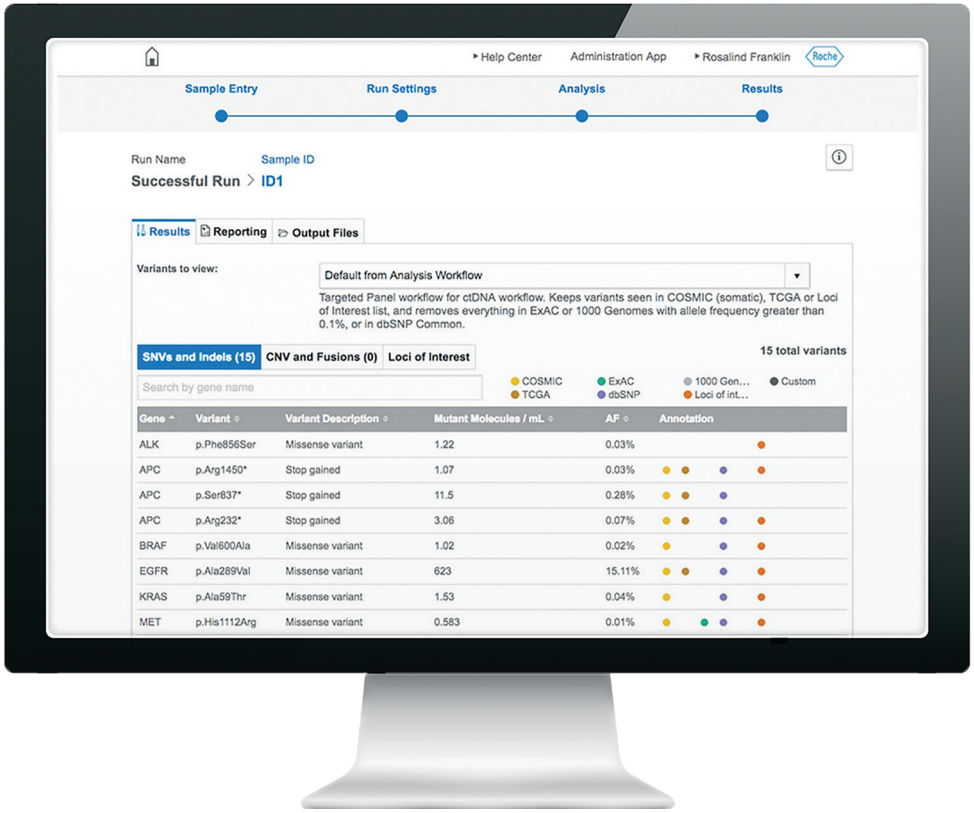
Performance metrics[4]

Mutant Allele Frequency/ Copy Number	SNVs		Indels		Fusions		CNVs**	
	0.5%*		1.0%*		1.0%			
AVENIO ctDNA Kit V2	Sensitivity	PPV	Sensitivity	PPV	Sensitivity	PPV	Sensitivity	PPV
Targeted	**>99%**	**>99%**	**>99%**	**>99%**	**>99%**	**>99%**	**SD**	**>99%**
Expanded	**>99%**	**>95%**	**>99%**	**>99%**	**>99%**	**>99%**	**SD**	**>99%**
Surveillance	**>99%**	**>99%**	**>99%**	**>99%**	**>99%**	**>99%**	**SD**	**>99%**

SD: Sample dependent
* Detects variants down to 0.1%
**Can detect ERBB2, EGFR, and MET CNVs. Performance dependent on input sample type and input concentration (10 ng – 50 ng per reaction).

Performance samples: Seraseq ctDNA Complete Mutation Mixes (SeraCare), healthy donor cfDNA.

Sensitivity and Positive Predictive Value (PPV) metrics based on observed product performance. Sensitivity and PPV performance reported per variant. Sensitivity was determined using commercially available reference samples containing verified mutations at the stated allele frequencies. SNV performance data based on hotspot calls. The AVENIO ctDNA Analysis Kit V2 can achieve >99.99% per base specificity across each of the panels. Stated performance requires at least 40 million reads per sample for all AVENIO ctDNA Panels V2. Sequencing performed on an Illumina® NextSeq™ 500/550/550Dx instrument.



Robust, intuitive analysis and reports

With a focus on clarity and simplicity, the AVENIO ctDNA Analysis Software helps minimize the complexity and effort required to generate extensive insights from oncology sequencing data. The system provides analytical details and reports on variant calling and sequencing quality metrics.

Variant Calling

- Genes with identified variants
- Mutation class of detected variants (SNVs, Indels, Fusions, CNVs)
- Mutation frequency and number of mutant molecules detected
- Annotation from public databases

Sequencing Quality Metrics

- Sequencing depth
- Coverage uniformity
- On-target rate

Contact your local Roche representative about bringing NGS liquid biopsy testing with the AVENIO ctDNA Analysis Kits into your lab.

With a growing portfolio of AVENIO next-generation sequencing products, Roche aims to make sequencing simple and accessible for everyday use.

1. Newman AM, Lovejoy AF, Klass DM, et al. Integrated digital error suppression for improved detection of circulating tumor DNA. Nature Biotechnology. 2016;34(5):547–555. doi:10.1038/nbt.3520.
2. Newman AM, Bratman SV, To J, et al. An ultrasensitive method for quantitating circulating tumor DNA with broad patient coverage. Nature Medicine. 2014;20(5):548–554. doi:10.1038/nm.3519.
3. National Comprehensive Cancer Network. http://www.nccn.org. Accessed August 28, 2023.
4. Data on file with Roche.

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